

PATENT COOPERATION TREATY

From the  
INTERNATIONAL SEARCHING AUTHORITY

REC'D 24 MAY 2005  
WIPO

To:  
Awapatent AB  
Box 5117  
200 71 Malmö  
Sweden

PCT

WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY  
(PCT Rule 43bis.1)

Date of mailing  
(day/month/year) 17 -05- 2005

Applicant's or agent's file reference  
21018060

FOR FURTHER ACTION

See paragraph 2 below

|   |  |  |
|---|--|--|
| International application No.<br>PCT/SE 2005/000054 | International filing date (day/month/year)<br>19.01.2005 | Priority date (day/month/year)<br>04.02.2004 |
|---|--|--|

International Patent Classification (IPC) or both national classification and IPC A61K 31/4025, 31/155, 31/195,  
C07D207/26, 211/98, 401/12, 403/12, 215/00, A61P 19/00, 37/00, 21/00

Applicant  
Active Biotech AB et al

1. This opinion contains indications relating to the following items:

- Box No. I Basis of the opinion
- Box No. II Priority
- Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- Box No. IV Lack of unity of invention
- Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- Box No. VI Certain documents cited
- Box No. VII Certain defects in the international application
- Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further opinions, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

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WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/SE 2005/000054

Box No. I Basis of this opinion

1. With regard to the language, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.  
 This opinion has been established on the basis of a translation from the original language into the following language, \_\_\_\_\_, which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).
2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
  - a. type of material  
 a sequence listing  
 table(s) related to the sequence listing
  - b. format of material  
 in written format  
 in computer readable form
  - c. time of filing/furnishing  
 contained in the international application as filed.  
 filed together with the international application in computer readable form.  
 furnished subsequently to this Authority for the purposes of search.
3.  In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY

International application No.  
PCT/SE 2005/000054

Box No. II Priority

1.  The following document has not yet been furnished:

copy of the earlier application whose priority has been claimed (Rules 43bis.1 and 66.7(a)).  
 translation of the earlier application whose priority has been claimed (Rules 43bis.1 and 66.7(b)).

Consequently it has not been possible to consider the validity of the priority claim. This opinion has nevertheless been established on the assumption that the relevant date is the claimed priority date.

2.  This opinion has been established as if no priority had been claimed due to the fact that the priority claim has been found invalid (Rules 43bis.1 and 64.1). Thus for the purposes of this opinion, the international filing date indicated above is considered to be the relevant date.

3. Additional observations, if necessary:

The priority is considered valid.

WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/SE 2005/000054

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The question whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

the entire international application

claims Nos. 14 - 16

because:

the said international application, or the said claims Nos. 14 - 16  
relate to the following subject matter which does not require an international preliminary examination (*specify*):

See PCT Rule 67.1.(iv).: Methods for treatment of the human or animal body by surgery or therapy, as well as diagnostic methods.

the description, claims or drawings (*indicate particular elements below*) or said claims Nos. \_\_\_\_\_  
are so unclear that no meaningful opinion could be formed (*specify*):

The claims, or said claims Nos. \_\_\_\_\_ are so inadequately supported  
by the description that no meaningful opinion could be formed.

no international search report has been established for said claims Nos. \_\_\_\_\_

the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

the written form

has not been furnished

does not comply with the standard

the computer readable form

has not been furnished

does not comply with the standard

the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in the Annex C-bis of the Administrative Instructions.

See Supplemental Box for further details.

**WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY**

|                               |
|-------------------------------|
| International application No. |
| PCT/SE 2005/000054            |

|   |        |             |        |             |     |  |        |  |    |                     |        |             |     |  |        |  |    |                               |        |             |     |  |        |  |    |
|---|--------|-------------|--------|-------------|-----|--|--------|--|----|---------------------|--------|-------------|-----|--|--------|--|----|-------------------------------|--------|-------------|-----|--|--------|--|----|
| <b>Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</b>   |        |             |        |             |     |  |        |  |    |                     |        |             |     |  |        |  |    |                               |        |             |     |  |        |  |    |
| <p><b>1. Statement</b></p> <table> <tr> <td align="center">Novelty (N)</td> <td align="center">Claims</td> <td align="center"><u>1-13</u></td> <td align="center">YES</td> </tr> <tr> <td></td> <td align="center">Claims</td> <td align="center"></td> <td align="center">NO</td> </tr> <tr> <td align="center">Inventive step (IS)</td> <td align="center">Claims</td> <td align="center"><u>1-13</u></td> <td align="center">YES</td> </tr> <tr> <td></td> <td align="center">Claims</td> <td align="center"></td> <td align="center">NO</td> </tr> <tr> <td align="center">Industrial applicability (IA)</td> <td align="center">Claims</td> <td align="center"><u>1-13</u></td> <td align="center">YES</td> </tr> <tr> <td></td> <td align="center">Claims</td> <td align="center"></td> <td align="center">NO</td> </tr> </table> |        | Novelty (N) | Claims | <u>1-13</u> | YES |  | Claims |  | NO | Inventive step (IS) | Claims | <u>1-13</u> | YES |  | Claims |  | NO | Industrial applicability (IA) | Claims | <u>1-13</u> | YES |  | Claims |  | NO |
| Novelty (N)   | Claims | <u>1-13</u> | YES    |             |     |  |        |  |    |                     |        |             |     |  |        |  |    |                               |        |             |     |  |        |  |    |
|   | Claims |             | NO     |             |     |  |        |  |    |                     |        |             |     |  |        |  |    |                               |        |             |     |  |        |  |    |
| Inventive step (IS)   | Claims | <u>1-13</u> | YES    |             |     |  |        |  |    |                     |        |             |     |  |        |  |    |                               |        |             |     |  |        |  |    |
|   | Claims |             | NO     |             |     |  |        |  |    |                     |        |             |     |  |        |  |    |                               |        |             |     |  |        |  |    |
| Industrial applicability (IA)   | Claims | <u>1-13</u> | YES    |             |     |  |        |  |    |                     |        |             |     |  |        |  |    |                               |        |             |     |  |        |  |    |
|   | Claims |             | NO     |             |     |  |        |  |    |                     |        |             |     |  |        |  |    |                               |        |             |     |  |        |  |    |
| <p><b>2. Citations and explanations:</b></p> <p>Documents cited in the International Search Report:</p> <p>D1: WO 99/63929 A3</p> <p>D2: WO 99/12912 A1</p> <p>D3: WO 93/16992 A1</p> <p>D4: EP 0325 397 A1</p> <p>The cited documents represent the general state of the art. The invention defined in claims 1-13 is not disclosed by any of these documents. The cited prior art does not give any indication that would lead a person skilled in the art to the claimed diureas. Therefore, the claimed invention is not obvious to a person skilled in the art. Accordingly, the invention defined in claims 1-13 is novel and is considered to involve an inventive step. The invention is industrially applicable.</p>   |        |             |        |             |     |  |        |  |    |                     |        |             |     |  |        |  |    |                               |        |             |     |  |        |  |    |